



<b>DEPARTMENT:</b> Clinical Operations Group	<b>POLICY DESCRIPTION:</b> Responsible Use of Generative Artificial Intelligence In Scholarly Work
<b>PAGE:</b> 1 of 2	<b>REPLACES POLICY DATED:</b>
<b>EFFECTIVE DATE:</b> July 1, 2024	<b>REFERENCE NUMBER:</b> COG.PUB.003
<b>APPROVED BY:</b> Ethics and Compliance Policy Committee	

**SCOPE:** This policy applies to all Company-affiliated entities.

**PURPOSE:** To provide guidance needed for the responsible use of Generative Artificial Intelligence (Gen AI) assistive technologies (such as Large Language Models (LLMs), multimodal AI systems, or similar technologies that generate synthetic text, images, or other content) when producing Scholarly Work.

**POLICY**

1. **Assurance of Awareness of Company Responsible AI Requirements.** Regardless of being an Author or not, any colleague or other individual expected or intending to use Gen AI assistive technologies in the drafting of Scholarly Work (defined in Policy COG.PUB.001 to include but not be limited to a conference presentation or poster, an article or other manuscript, case histories drafted to be published, editorials and columns, books and book chapters, abstracts and lemmas, visualizations, social media postings, websites and other outputs whether or not human readable) must, prior to using any Gen AI assistive technologies:
  - a. be aware of this policy; and
  - b. be aware of and adhere to any and all Company requirements regarding the use of such Gen AI assistive technologies, including but not limited to company approval of the technology itself as well as completion of any product-specific and company-required Responsible AI training.
  
2. **The Author(s) and Contributor(s) Must Differentiate Human Contributions from Non-Human Contributions and Disclose Such Differentiation As Part Of The Scholarly Work.**
  - a. Author(s) and Contributor(s) must identify any and all portions of their work product that had more than *de minimis* contribution from Gen AI assistive technologies. For example, when an AI technology receives solely a prompt from a human and produces complex written, visual, or other works in response, the creative control and other traditional elements of authorship and contributorship are determined and executed by the technology, not the human user. Even if Author(s) or Contributor(s) select or arrange Gen AI generated material in their own expressive way, any remaining derivations of that Gen AI output that contain more than a *de minimis* amount of the original AI generated output remains considered non-human generated. Of note, this applies to the content of the copyrightable work product; for example, if the use of the Gen AI assistive technology is only as a research aid (e.g. asking the Gen AI assistive technology to narrowing down articles for the Author(s)' literature search); such use would not need to be differentiated assuming the list itself is not part of the Scholarly Work.

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- b. The Author(s) must document any portions of the Scholarly Work that represent non-human authorship. This can be done in the Contributorship disclosures of the Scholarly Work or other supplemental notations that accompany the Scholarly Work.
  - c. When using sub-contractors to perform Authorship or Contributorship duties on behalf of the company, the obligation for the sub-contractor to identify and disclose to the company any more than *de minimis* contribution from Gen AI assistive technologies in the work product (whether on whole or in part) must be a requirement in the written agreement along with the ability for the company to reject such work product (or portions of the work product) at the company's discretion if the Generative AI produced material is insufficient to meet company needs.
  - d. The above differentiation and disclosure is a minimum standard noting that publishers may have additional requirements that the Corresponding Author(s) must also disclose.
3. **The Author(s) remain fully accountable for their final workproduct.** While the use of Gen AI assistive technologies as aids for authoring a Scholarly Work is not prohibited, however from an authorship accountability and disclosure standpoint its use is categorically no different than the use of any other aids. Specifically, for Gen AI assistive technologies Author(s) must do the following:
  - a. Prior to incorporating the results of Gen AI assistive technologies into their Scholarly Work, all Author(s) must carefully review and edit the output to assure it is complete, unbiased, not plagiarized, not substantially similar to or infringing on third-party intellectual property (IP) rights, and free of inaccuracies (such as false or inappropriate citations); and
  - b. The Author(s) must understand all conditions for use of the generated content, specifically any necessary licenses, permissions, and/or citation requirements.

**REFERENCES:**

1. Designation as Authors and Contributors in Scholarly Work Policy, [COG.PUB.001](#)
2. Responsible AI Policy, EC.031
3. Copyright Policy, [LL.GEN.002](#)
4. ICMJE updated the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals; January 2024 (<https://www.icmje.org/icmje-recommendations.pdf>)
5. Copyright Registration Guidance: Works Containing Material Generated by Artificial Intelligence [https://copyright.gov/ai/ai\\_policy\\_guidance.pdf](https://copyright.gov/ai/ai_policy_guidance.pdf)